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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,355	01/26/2001	David A. Zarling	A-68872-1/RFT/RMS/BTC	6076

7590 03/22/2004

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EXAMINER

LAMBERTSON, DAVID A

ART UNIT PAPER NUMBER

1636

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/771,355

Applicant(s)

ZARLING ET AL.

Examiner

David A. Lambertson

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Receipt is acknowledged of a reply to the previous Office Action, filed January 2, 2004.

Amendments were made to the claims.

Claims 10-15 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed June 30, 2003, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action, this Office Action is made FINAL.

#### ***Claim Rejections - 35 USC § 112***

Claims 10-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. **This rejection is maintained for the reasons set forth in the previous Office Action.**

#### ***Response to Arguments Concerning Claim Rejections - 35 USC § 112***

Applicant's arguments filed January 2, 2004 have been fully considered but they are not persuasive. Applicant provided the following grounds of traversal:

1. Applicant asserts that the specification discloses various Rad51 inhibitors as well as methods of p53 gene therapy. Applicant indicates that, not only are a number of small molecule inhibitors

Art Unit: 1636

of Rad51 described in the specification, but other small inhibitors could be isolated by employing routine activity screens.

Applicant's arguments are not convincing for the following reasons:

1. Applicant simply provides their opinion that the invention is enabled, and fails to address several of the references set forth in the Office Action that raise the issue of non-enablement of the invention. Specifically:

(a) Applicant does not address the issue of scope as it pertains to which cancers can or cannot be treated with Rad51 inhibitors. The Office provides several references discussing the complex nature of cancer, that it is not a single disease with a single etiology, but rather a broad range of diseases with entirely distinct causal mechanisms (see for example Pervaiz). This reference further teaches that there are a number of drawbacks to cancer treatments, such as the non-selectivity of cancer agents. Applicant fails to address how one of skill in the art would properly direct the Rad51 inhibitors to the proper cells so as to avoid improperly affecting normal cells. As such, with at least respect to the scope of cancers that can be treated by the claimed method, and the inability to properly target the inhibitors to the diseased cells, the invention does not meet the enablement requirement.

(b) The Pervaiz, as well as the Perez and Sarkadi references, also raise the issue of cellular resistance to anti-cancer agents, which Applicant fails to address. This is a very important aspect of cancer treatment because cancer is most often a chronic disease that requires long-term treatment (or treatment over a long period of time). Because Applicant fails to address how one of skill in the art would counteract multi-drug resistance, etc., in terms of the administration of

Art Unit: 1636

Rad51 inhibitors, the skilled artisan cannot make and use the invention. For this argument, Applicant has no clear response.

(c) Applicant also fails to address the argument of the affects of Rad51 inhibitors on non-cancer cells, where the regular DNA repair pathways will be inhibited. This can give rise to cancer in the normal cells, effectively causing the problem the method is designed to treat. The fact that there are no examples or working models of the claimed treatment method does not rectify the lack of teachings with regards to the concerns addressed in the state of the art.

In conclusion, Applicant fails to address any of the references set forth in the previous Office Action which raise issues as to the unpredictability, and thus the non-enablement, of the instantly claimed invention. Rather, Applicant simply provides an opinion that the claimed method would not require undue and unpredictable trial and error experimentation. This opinion is not sufficient to counter the number of references provided by the Office, which actually show the unpredictability of the claimed method of treating any cancer with an inhibitor for a single model. As such, Applicant's arguments are not convincing, and the enablement rejection is maintained.

***Allowable Subject Matter***

No claims are allowed.

Art Unit: 1636

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1636

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.  
AU 1636



**JAMES KETTER  
PRIMARY EXAMINER**